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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,957	02/19/2002	Yukio Kato	KATO=21	8967
1444	7590	06/30/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			LOCKARD, JON MCCLELLAND	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,957

Applicant(s)

KATO ET AL.

Examiner

Jon M Lockard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 22 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-10 (each in part), and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10 (each in part), and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/15/02, 4/29/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1647, Examiner Jon Lockard.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Election/Restrictions

Applicant's election with traverse of Group II (Claims 1-6, 8-10, and 16, (each in part)) in the Response filed 22 April 2004 drawn to the polypeptide of SEQ ID NO:4, a polypeptide with MTF activity encoded by a nucleic acid that hybridizes under stringent conditions to nucleic acid encoding SEQ ID NO:4, and to a fragment of SEQ ID NO:4 lacking the GPI anchor region is acknowledged. The traversal is on the grounds that Groups I through III all contain the same claims (1-6, 8-10, and 16) and that all of these claims are generic. This is not found persuasive. Applicant has provided no fact or argument; merely grouping inventions by effect doesn't make a generic claim in terms of the claimed inventions sharing a unifying technical feature. The traversal is also on the grounds that the technical feature linking the claimed inventions is evidence that the Applicants have found that MTF proteins have an ability to stimulate cartilage formation. This is not found persuasive. Applicants have failed to point out a unifying technical

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feature; a mechanism of action is not a technical feature. Applicants argue that groups I-III and IV-VI have share some of the same claims (claim10 for example). There is no unifying special technical feature between Groups I-III and IV-VI as they pertain to claim 10, as claim 10 is drawn either to a polypeptide (Groups I-III) or a nucleic acid (Groups IV-VI). The polypeptides of Groups I-III and the nucleic acids of Groups IV-VI are structurally and functionally different compounds, each of which can be made and used without the other compound. Lack of unity is shown because these compounds lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility. Lastly, Applicants argument of Groups VII and VIII is moot, as neither Group was elected.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7 and 11-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 22 April 2004.

Claims 1-6, 8-10, and 16 (each in part) are under consideration in the instant application and read upon the elected group of the polypeptide of SEQ ID NO:4, a polypeptide with MTF activity encoded by a nucleic acid that hybridizes under stringent conditions to nucleic acid encoding SEQ ID NO:4, and to a fragment of SEQ ID NO:4 lacking the GPI anchor region.

Drawings

The drawings are objected to because Figures 2-7 are too dark for the Examiner to reasonably interpret. Corrected drawing sheets are required in reply to the Office action to avoid

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abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 1 is objected to because of the following informalities: spelling mistake "cartridge". Appropriate correction is required.

Claims 1-33 are objected to because of the following informalities: Claims 2 and 3 encompass non-elected inventions, e.g., p76 protein in claim 2 and SEQ ID NOS: 2&15 in claim 3. Appropriate correction is required.

Claims 8-10 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

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claim(s) in independent form. In the instant case the intended use recited in claims 8-10 does not further limit the compound of claim 1.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 and 16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-6 and 16 are drawn to MTf (Claims 1-4) and a soluble form of MTf (claims 5-6 and 16), all of which are unaltered, naturally occurring compounds. Thus, they are not articles of "manufacture". These rejections may be obviated by amending the claims to read "an isolated membrane-bound transferring-like protein (MTf)", "isolated human p97 protein", "an isolated protein having the amino acid sequence of SEQ ID NO:4", "an isolated protein demonstrating MTf activity", "isolated human p97 protein", "isolated soluble MTf", "isolated soluble MTf", and "isolated MTf which lacks the GPI anchor region", so long as there is support for the amendment in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 8-10, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite because the phrase "cartridge formation stimulator" is unclear as the metes and bounds of this phrase are

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not defined in the Specification nor are limitations provided in the claim to clearly define said phrase.

Claim 1 is further rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it is unclear if Applicants are claiming a compound, a composition, or something entirely different.

Claims 2-6 and 8-10 are indefinite because there is no antecedent for the limitation "chondrogenesis stimulator" recited in line 1 of each of the claims. Claim 1, from which claims 2-6 and 8-10 depends, does not recite a "chondrogenesis stimulator".

Claim 2 is rejected as being indefinite because it is unclear if the DNA hybridizes with a DNA encoding rabbit p76 or human p97, or any p76 or p97 (See line 6 of the claim).

Claims 2 and 3 are rejected as being indefinite because it is unclear of the meaning of the term "the" MTf activity, e.g., in part 4 of claim 3. Since the term MTf has conventionally been used as the abbreviation for melanotransferin (p97), known as a tumor antigen expressed at high levels in melanoma and other tumors (See page 8, lines 10-13 of the Instant Application), it is unclear what "the" activity of this protein the claim is referring.

Claims 2 and 3 are further rejected as being indefinite as there is no limiting definition of stringent hybridization conditions in the Specification, and the metes and bounds of that which will hybridize are dependent upon the conditions under which the hybridization is performed. The discussion of such at page 5 of the Specification is noted but vague, fails to breathe life and meaning into the term, is exemplary rather than limiting, and thus is insufficient to render the claims definite.

Claim 8 is rejected as being indefinite because it is not clear whether the limitation “used in combination with insulin or an insulin-like growth factor” of claim 8 is intended to indicate an additional component of a composition, or is merely an intended use.

Claim 8 is further rejected as being indefinite as it is unclear what kinds of substances are to be included in the definition of an “MTf activating agent”, since the only substance specifically disclosed in the Specification as an example of an “MTf activating agent” is the substance present in the conditioned media (See page 15, line 10), and there is no description of other substances having this activity.

Claim 9 is indefinite for reciting “an insulin-like growth factor”. Without knowing which insulin-like growth factor, the metes and bounds of the claim cannot be determined.

Claims 1, 5, 6, 8, and 16 are rejected as being indefinite as there is no limiting definition of MTf in the Specification. The discussion of such (See page 8, lines 4-7) in the Specification is noted but vague, fails to breathe life and meaning into the term, is exemplary (See also page 8, lines 7-17) rather than limiting, and thus is insufficient to render the claims definite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-6, 8-10, and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Jefferies et al. (WO 94/01463). Jefferies et al. teach a human p97 protein (See page 2, lines 23-24) that is membrane-associated (See page 2, line 29) and transferrin-like (See page 3, lines 3-8). They teach a human p97 protein that shares 100% sequence homology with SEQ ID NO:4 of the Instant Application (See pages 102-106, SEQ ID NO:1, GenBank Accession No. AAR47899). Further, Jefferies et al. teach a soluble form of p97 (See page 9, lines 17-23) and that the soluble form of p97 lacks the GPI anchor region (See page 9, lines 11-15; Page 10, line 35 - Page 11, line 7; See also Figure 14).

Summary

Claims 1-6, 8-10, and 16 are hereby rejected.

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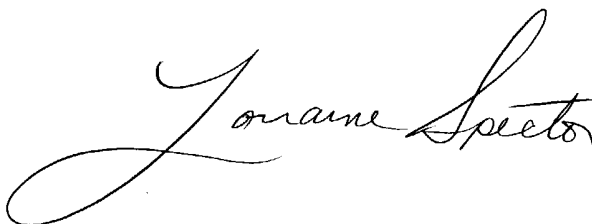
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **<http://pair-direct.uspto.gov>**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
June 25, 2004

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in dark ink and is positioned above the printed name and title.

**LORRAINE SPECTOR
PRIMARY EXAMINER**